(c) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(d) The Chief and Assistant Chief, Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 506 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.75 Designation of official master and working standards for antibiotic drugs.

The following officials are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Research Resources, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Research Resources, CDER.

[49 FR 27315, July 3, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.76 Certification of antibiotic drugs.

The following officials are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(d) The Chief and Assistant Chief, Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use:

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(b) The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use contained in medical devices.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14935, Apr. 16, 1984; 54 FR 8319, Feb. 28, 1989]

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act:

(i) The Director and Deputy Director, and Deputy Director (Medical and